

COMPLETE LISTING OF CLAIMS INCLUDING AMENDMENTS

1. (currently amended) A method for ~~treating a disease by~~ delivering a therapeutic agent into the inner ear of a living subject through the ~~round window niche and the round window membrane thereof~~, said method comprising:

providing a drug delivery unit ~~having a volume of between 0.1 mm³ and 250 mm³~~
wherein the drug delivery unit comprises at least one biodegradable synthetic controlled release comprising a carrier material adapted for delivery of a therapeutic agent in nanogram to microgram quantities, and at least one a therapeutic agent in nanogram to microgram quantities combined therewith, wherein said carrier material releasing said provides for controlled release of the therapeutic agent from said drug delivery unit over time when said drug delivery unit is placed in said round window niche of said subject;
and

placing inserting said drug delivery unit directly into the round window niche of the subject such that said unit is positioned completely within the round window niche, at least partially in said round window niche of said subject; and

allowing said drug delivery unit in said round window niche to release said wherein the therapeutic agent therefrom so that said therapeutic agent comes in contact is released from the drug delivery unit, contacts the with said round window membrane; passes therethrough, and enters said and passes into the inner ear.

2. - 25. (cancelled)

26. (currently amended) The method of claim 1 wherein said drug delivery unit has a ~~length of between about 0.5 mm and 20 mm~~ volume of between 0.1 mm³ and 250 mm³.

27. (currently amended) The method of claim 1 wherein said drug delivery unit has a ~~diameter of between about 0.5 mm and 4 mm~~ is configured as a pellet, disk, tablet, plate, sphere, cube, cylindrical unit, strand, plug, paste, or amorphous mass.

28. **(currently amended)** The method of claim 1 wherein said ~~drug delivery unit~~ has a length of between about 0.5 mm and 20 mm and a diameter of between about 0.5 mm and 4 mm carrier material is capable of delivering the therapeutic agent to the inner ear in nanogram to microgram quantities.

29. **(previously amended)** The method of claim 1 wherein said therapeutic agent is present in a quantity of between about 10 wt% and 40 wt% of the total weight of the drug delivery unit.

30 - 47. **(cancelled)**

48. **(currently amended)** The method of claim 1 wherein the ~~biodegradable synthetic controlled-release~~ carrier material is an injectable material.

49. **(previously added)** The method of claim 1 wherein said placing of said drug delivery unit is done by injection.

50. **(currently amended)** The method of claim 1 wherein said therapeutic agent is released over ~~at least~~ a period of 24 hours.

51. **(previously added)** The method of claim 1 wherein said therapeutic agent is released over a period of hours.

52. **(previously added)** The method of claim 1 wherein said therapeutic agent is released over a period of months.

53. **(currently amended)** The method of claim 1 wherein said ~~synthetic controlled-release~~ carrier material comprises a polymer.

54. **(currently amended)** The method of claim 1 wherein said ~~synthetic controlled-release~~ carrier material comprises a polyanhydride material.

55. **(currently amended)** The method of claim 1 wherein said ~~synthetic controlled-release~~ carrier material comprises a polyorthoester material.

56. **(currently amended)** The method of claim 1 wherein said ~~synthetic controlled-release~~ carrier material comprises hydroxypropylmethyl cellulose.

57. **(currently amended)** The method of claim 1 wherein said ~~synthetic controlled-release~~ carrier material comprises hydroxyethyl cellulose.

58. **(currently amended)** The method of claim 1 wherein said ~~synthetic controlled-release~~ carrier material comprises hydrophilic microspheres.

59. **(currently amended)** The method of claim 1 wherein said ~~synthetic controlled-release~~ carrier material comprises a bioadhesive material.

60. **(previously added)** The method of claim 1 wherein said drug delivery unit is a multiphased composite drug delivery unit.

61 - 62. (cancelled)

63. **(previously added)** The method of claim 1 wherein said therapeutic agent is selected from the group consisting of urea, mannitol, sorbitol, glycerol, lidocaine, xylocaine, epinephrine, immunoglobulins, sodium chloride, steroids, heparin, hyaluronidase, aminoglycoside antibiotics, antioxidants, neurotrophins, nerve growth factors, various therapeutic peptides, and polysaccharides.

64. **(previously added)** The method of claim 63 wherein said therapeutic agent is an aminoglycoside antibiotic.

65. **(previously added)** The method of claim 64 wherein said aminoglycoside antibiotic is gentamycin.

66. **(previously added)** The method of claim 1 wherein said release of said therapeutic agent is achieved by osmosis, diffusion, active/passive transport, or a combination thereof.

67. **(new)** The method of claim 1, wherein the carrier material is biodegradable.

68. **(new)** The method of claim 1, wherein the carrier material is synthetic.

69. **(new)** The method of claim 1, wherein the drug delivery unit comprises a soft, semi-soft, or pliable carrier material.

70. **(new)** The method of claim 1, wherein release of the therapeutic agent from the drug delivery unit is without inadvertent delivery to other tissue regions outside the round window niche.

71. **(new)** A method for delivering a therapeutic agent into the inner ear of a living subject, said method comprising:

providing a drug delivery unit comprising a carrier material and a therapeutic agent combined therewith, wherein said carrier material provides for controlled release of the therapeutic agent from said drug delivery unit over time, and further wherein said drug delivery unit is configured as a pellet, disk, tablet, plate, sphere, cube, cylindrical unit, strand, plug, paste, or amorphous mass; and

inserting said drug delivery unit directly into the round window niche of the subject such that said unit is positioned either partially or completely within the round

window niche, wherein the therapeutic agent is released from the drug delivery unit, contacts the round window membrane and passes into the inner ear.

72. (new) The method of claim 71 wherein said therapeutic agent is released over a period of 24 hours.

73. (new) The method of claim 71 wherein said therapeutic agent is released over a period of hours.

74. (new) The method of claim 71 wherein said therapeutic agent is released over a period of months.

75. (new) The method of claim 71 wherein said carrier material comprises a polymer.

76. (new) The method of claim 71, wherein the carrier material is biodegradable.

77. (new) The method of claim 71, wherein the carrier material is synthetic.

78. (new) The method of claim 71, wherein release of the therapeutic agent is achieved by osmosis, diffusion, active/passive transport, or a combination thereof.

79. (new) The method of claim 71, wherein the drug delivery unit comprises a soft, semi-soft, or pliable carrier material.

80. (new) The method of claim 71 wherein said therapeutic agent is selected from the group consisting of urea, mannitol, sorbitol, glycerol, lidocaine, xylocaine, epinephrine, immunoglobulins, sodium chloride, steroids, heparin, hyaluronidase, aminoglycoside antibiotics, antioxidants, neurotrophins, nerve growth factors, various therapeutic peptides, and polysaccharides.

81. **(new)** The method of claim 80, wherein the therapeutic agent is an aminoglycoside antibiotic.

82. **(new)** The method of claim 81, wherein the aminoglycoside antibiotic is gentamycin.